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10/735,808

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Jay Miazga

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EXAMINER

HEITBRINK, JILL LYNNE

ART UNIT

PAPER NUMBER

1791

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/735,808 | Applicant(s) MIAZGA ET AL. | |
| | Examiner Jill L. Heitbrink | Art Unit 1791 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45, 47, 48 and 50-65 is/are pending in the application.
- 4a) Of the above claim(s) 1-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-45, 47, 48 and 50-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. In view of the Pre-Appeal Brief Request for Review filed on Dec. 11, 2007, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

2. Claims 1-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 39, 42, 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Lieber et al. Pat. No. 5,029,585.

5. Lieber discloses forming a first portion of a flexible carrier from a first quantity of elastic material (col. 5, lines 35-42) with the first portion having a channel (19). A flexible member is positioned in the channel (col. 7, lines 13-20). The channel has a lip portion (see opening 75 shown in Fig. 5) toward an opening of the channel which would inherently retain the flexible member in the channel. A second portion of the flexible carrier is formed by disposing an uncured second quantity of elastic material in the channel to at least partially cover the portion of the flexible member positioned in the channel (col. 7, line 65-col. 8, line 2). The second material is at least partially cured to bond the second portion of the flexible carrier to the first portion of the flexible carrier

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(col. 8, lines 2-5). The electrodes are bendable from a first shape to a second shape since they extend from one channel into another channel. The first and second portion of the flexible catheter having a durometer shore A hardness within the range of claim 43 is inherent since polyvinylchloride is within the range.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 40, 41 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lieber et al. Pat. No. 5,029,585 taken together with Honeyman Pat. No. 3,901,965.

8. Honeyman teaches a lumen formed by filling a first mold assembly with a first quantity of elastic material. It would have been obvious to a person of ordinary skill in the art to form the lumen in Lieber by filling a first mold assembly since this type of molding is known for producing catheters with multiple lumens. Lieber discloses the thermoplastic polymeric material 81 being injection molded into the lumen (col. 8, lines 2-4). It would have been obvious to a person of ordinary skill in the art of injection molding that the process would include positioning the lumen in a mold assembly to receive the uncured thermoplastic polymeric material 81. The compressing of the first portion (lumen) against the second mold (injection molding) to seal the channel and contain the uncured second quantity of the elastic material in the channel during curing

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of the second quantity of elastic material would have been obvious in Lieber since the material extending from the opening would cause tissue abrasion and blood clot formation (col. 8, lines 44-48). The examiner noted that the Lieber col. 8, lines 23-25 is referring to the material not being deformed during the extruding and pressing of the material into the cavity, this is not during the closing of the injection mold. The first and second portion of the flexible catheter having a durometer shore A hardness within the range of claim 43 would have been obvious to a person of ordinary skill in the art since polyvinylchloride is within the range.

9. Claims 39-45, 47, 48, 50-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bishay et al (U.S. Patent Application Publication 2001/0021869) taken together with either O'Brien et al. Pat. No. 6,027,679 or Leighton Pat. No. 4,339,407.

10. Bishay discloses a method of forming a flexible support member reading on claim 44. Bishay teaches molding a portion of the support member including a cable channel and first and second engagement members for couplings having first and second surfaces, laying a bundled link and individual links in the channel, and attaching a second portion with a second surface in an overmold process. It is the Examiner's position that layered surfaces in direct contact are coplanar. Specifically the top surface of the first surface and the bottom surface of the second surface contact each other in a shared plane (coplanar). See paragraph [0103] and Fig. 23. Bishay teaches a cylindrical shape for an engagement member, as required by claim 45. See paragraph [0109] and Fig. 26. Bishay teaches link portions spanning to first and second

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engagement members, as required by claims 57 and 58. This is illustrated by reference character 250 in Fig. 23. Bishay teaches a deformable member as a cable harness, as required by claim 61. See paragraph [0103]. Bishay teaches the use of Santopene® in paragraph [0103]. As noted above in the discussion of claims 43 and 50, Santopene® meets the durometer requirements of claim 47. Lieghton and O'Brien each teach the forming of electronic encapsulated wiring by molding a first portion, inserting the wiring and molding a second portion which is cured to the first portion and the use of lips or protrusions. It would have been obvious to a person of ordinary skill in the art to mold the coupler support of Bishay using the known molding steps for electron couplers since these steps are known to provide encapsulated wiring and may have been considered within the steps of overmolding. Each of Bishay [0103] and O'Brien (Fig. 3) teach at least two members, first elongate flexible member and elongate deformable member, inserted into a channel,

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jill L. Heitbrink whose telephone number is (571) 272-1199. The examiner can normally be reached on Monday-Friday 9 am -2 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra Gupta can be reached on (571) 272-1316. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jill L. Heitbrink/
Primary Examiner, Art Unit 1791

jlh